K000430

FEB 2 5 2000

# SUMMARY OF SAFETY AND EFFECTIVENESS

## COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
4633 E.La Palma Avenue
Anaheim, CA 92807
714-779-3650

4611 Northland Dr.
Minneapolis, MN
612-391-9078

Debra Kridner, Director of Regulatory/Clinical Affairs

## DEVICE NAME

AFFINITY®NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Carmeda® BioActive Surface

## NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

- AFFINITY® Hollow Fiber Oxygenator (K932252)
- MAXIMA PLUS® Hollow Fiber Oxygenator with Carmeda® BioActive Surface with Plasma Resistant Fiber (K941473)

## DESCRIPTION OF DEVICE

The Medtronic AFFINITY®NT Oxygenator with Carmeda® BioActive Surface is a single-use, disposable, sterile, nonpyrogenic fluid path, gas exchange device with a self contained, venous-side heat exchanger for regulating blood temperature. The microporous polypropylene hollow fibers are wound around a core and encased in a plastic outer shell. Oxygen flows through the hollow fibers and blood flows from the stainless steel heat exchanger around the hollow fibers. Gas exchange occurs by diffusion across the hollow fiber membrane. A gas outlet is provided for scavenging, and a gas vent prevents over pressurization.

The modification to the currently marketed AFFINITY® Hollow Fiber Oxygenator is to coat the primary blood contact surfaces with a non-leaching, thromboresistant bioactive coating (Carmeda® ).

## STATEMENT OF INTENDED USE

The Medtronic AFFINITY®NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Carmeda® BioActive Surface is intended for use in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

## STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Medtronic AFFINITY® Hollow Fiber Oxygenator is intended for use in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The Medtronic MAXIMA PRF® Hollow Fiber Oxygenator with Carmeda® BioActive Surface with Plasma Resistant Fiber is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from blood and is designed to operate at blood flow rates between 1 and 7 liters per minute for periods up to six hours.

## STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristic comparison is provided in the following section, "Determination of Substantial Equivalence".

## DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"Special 510(k)"** is being submitted for a modification to the AFFINITY® Hollow Fiber Oxygenator. The modification to the current AFFINITY®NT Hollow Fiber Oxygenator is to coat the primary blood contact surfaces with a non-leaching, biocompatible coating (Carmeda®). In determining substantial equivalence of the AFFINITY®NT Oxygenator with Carmeda® BioActive Surface the decision-making process follows the 510(k) "Substantial Equivalence" flow diagram and is presented as follows:

The AFFINITY®NT Oxygenator with Carmeda® BioActive Surface is being **"compared to the following Marketed Devices"**:

- AFFINITY® Hollow Fiber Oxygenator (K932252)
- MAXIMA PRF® Hollow Fiber Oxygenator with Carmeda® BioActive Surface with Plasma Resistant Fiber (K941473)

AFFINITY®NT Oxygenator with Carmeda® BioActive Surface has the **"same indications statement and intended uses"** as the:

- AFFINITY® Hollow Fiber Oxygenator (K932252)

AFFINITY®NT Oxygenator with Carmeda® BioActive Surface has **"new technological characteristics (e.g., materials and manufacturing processes)"** from the current Medtronic AFFINITY® Hollow Fiber Oxygenator and MAXIMA PRF® Hollow Fiber Oxygenator with Carmeda® BioActive Surface with Plasma Resistant Fiber. The new technological characteristic for the AFFINITY® Hollow Fiber Oxygenator is solely the coating material of the blood pathway;

- Carmeda®

The technological characteristic of Carmeda® BioActive Surface coating the blood path is common to other adult oxygenators currently in commercial distribution as follows:

- MAXIMA PRF® Hollow Fiber Oxygenator with Carmeda® BioActive Surface with Plasma Resistant Fiber (K941473)

This technological characteristic **"could affect the safety and effectiveness of the device"**. However these **"new technological characteristics do not raise new types of safety or effectiveness questions"**. In addition, **"there are accepted scientific methods which exist for assessing effects of these new technological characteristics"**. These scientific methods are provided in the following oxygenator standards;

- ISO/DIS 7199 (ISO/TC 150/SC 2) International Standard titled "Cardiovascular implants and artificial organs - Blood-gas exchangers"
- BG7199-1996 (proposed new American National Standard) titled, "Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)"
- ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Guidance on selection of tests; First Edition, 1992-04-15
- Bioactivity Analysis, Leaching Analysis, Coverage Analysis

**"Performance data to assess the effects of these new technological characteristics"** has been performed. These **"performance data demonstrate"** that the AFFINITY®NT Oxygenator with Carmeda® BioActive Surface is substantially equivalent to other marketed hollow fiber oxygenators.

The biocompatibility testing and in vitro bench testing demonstrated that when compared to the predicate device the AFFINITY®NT Oxygenator with Carmeda® BioActive Surface does not significantly affect safety and effectiveness and is substantially equivalent to other commercially distributed hollow fiber oxygenators. The in vitro bench testing included analysis of:

- **Coating Characteristics**
  - Leaching
  - Bioactivity
  - Coverage
- **Physical Characteristics**
  - Blood Pathway Integrity
  - Heat Exchanger Fluid Pathway Integrity
  - Blood Volumes
  - Connectors
- **Performance Characteristics**
  - Oxygen and Carbon Dioxide Transfer Rates
  - Time Dependent Performance Changes
  - Heat Exchanger Performance Factor
  - Pressure Drop
  - Gas Side Pressure Drop
  - Priming Evaluation
  - Blood Cell Damage
  - Plasma Breakthrough

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Ms. Debra Kridner
Director of Regulatory/Clinical Affairs
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Re: K000430
Affinity® NT Hollow Fiber Oxygenator with Plasma Resident Fiber with Carmeda® BioActive Surface
Regulatory Class: III (three)
Product Code: DTZ
Dated: February 7, 2000
Received: February 9, 2000

Dear Ms. Kridner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use

**510(k) Number (if known):** K000430

**Device Name:**

AFFINITY®NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Carmeda® BioActive Surface

**Indications For Use:**

The Medtronic AFFINITY®NT Hollow Fiber Oxygenator with Plasma Resistant Fiber with Carmeda® BioActive Surface is intended for use in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000430

Prescription Use X OR Over-The Counter Use____
(Per 21 CFR 801.109)